MAY - 5 2000

510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K000897.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807

Contact: Cindy Morrow
Sr. Regulatory Specialist
(408) 954-2694

Summary date: March 17, 2000

Device Name/Classification (21 CFR 807.92(a)(2))

Name: CaliBRITE™ PerCP-Cy5.5 beads and FACSComp™ Software

Classification: Accessory to a Class II Device

Substantially Equivalent*/Predicate Device (21 CFR 807.92(a)(3))

CaliBRITE™ PerCP-Cy5.5 beads and FACSComp™ are substantially equivalent to CaliBRITE™ beads with FACSComp™ (K973483), cleared to market on February 17, 1998.

Device Description (21 CFR 807.92(a)(4))

CaliBRITE PerCP-Cy5.5 beads and FACSComp software are intended for use on BD Biosciences flow cytometers FACStrak™, FACScan™, FACSort™ or FACSCalibur™ equipped with a 488 nm blue laser and the optional 635 nm red laser. They are used to optimally adjust instrument photomultiplier tube (PMT) settings, align the blue laser and red laser, set fluorescence compensation, and monitor instrument sensitivity. This product is recommended for instrument set up prior to running all BD Biosciences clinical software applications for flow cytometers. CaliBRITE PerCP-Cy5.5 beads are provided in single vials along with a bottle of bead dilution buffer. They can be used with the other CaliBRITE beads, including unlabeled, FITC-, PE-, APC-, and/or PerCP-labeled beads.

* The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Intended Use (21 CFR 807.92(a)(5))

For setting up the flow cytometer and monitoring instrument performance prior to performing reticulocyte enumeration or immunophenotyping applications.

Technological Characteristics (21 CFR 807.92(a)(6))

CaliBRITE PerCP-Cy5.5 beads and FACSComp software, when used with unlabeled, FITC-, PE-, PerCP- and APC-labeled beads are substantially equivalent to CaliBRITE beads and FACSComp software described in K973483 and cleared on February 17, 1998 as a Class II accessory device for flow cytometry. The bead product is composed of a vial of beads and a bottle of bead dilution buffer to set up the third fluorescence detector.

Performance Data (21 CFR 807.92(b)(1) and (2))

Performance of this product was established by testing at Becton Dickinson Immunocytometry Systems laboratories in San Jose, California.

Studies performed:

- Stability

  Storage stability of beads was determined to be 7 months under the conditions of use.

  Once diluted, the mixed-bead preparations are stable for 1 hour at room 25°C and for 8 hours at 2-8°C.

- Reproducibility

  Between bead lots.

  Within the set up options of lyse and wash (LW) and lyse no wash (LNW) across colors.

  Reproducibility was found to be equivalent to the predicate device.

Conclusions from Performance Data (21 CFR 807.92(b)(3))

The results of the design verification studies demonstrate that the device is as safe and effective as the predicate device.

Cindy Morrow.
Sr Regulatory Specialist

3.17.00
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 5 2000

Ms. Cindy Morrow
Senior Regulatory Specialist
BD Biosciences
2350 Qume Drive
San Jose, California 95131

Re: K000897
Trade Name: CaliBRITE™ PerCP-Cy5.5 Beads and FACSComp™ Software
Regulatory Class: II
Product Code: GKZ
Dated: March 17, 2000
Received: March 21, 2000

Dear Ms. Morrow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K000897

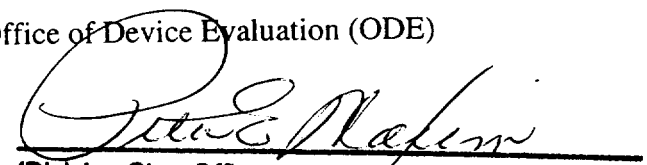
Device Name: FACSComp™ Software and CaliBRITE™ PerCP-Cy5.5 Beads

Indications for Use:

- For the FACS® family of flow cytometers (FACStrak™, FACScan™, FACSort™ and FACSCalibur™).
- An accessory device for instrument setup prior to performing reticulocyte enumeration and immunophenotyping.
- For adjusting instrument settings: aligning the signal from the blue and the optional red laser (FL4 Option), setting the photomultiplier tube (PMT) voltages, and monitoring instrument performance over time.
- For automatically setting the fluorescence compensation of the detectors to adjust for spectral overlap of fluorescent signals.
- For monitoring the sensitivity of the side scatter (SSC) and fluorescence (FL1, FL2, FL3, and FL4) detectors and verifying adequate separation of system noise from forward scatter (FSC) signals.
- For in vitro diagnostic use.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000897

Prescription Use ✓ Or Over-the-Counter Use _____

(Per 21 CFR § 801.109)